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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,131	11/01/2003	Martin T. Gerber	P0011610.00	2892
27581	7590	08/08/2007		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER LACYK, JOHN P	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 08/08/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/698,131

Applicant(s)

GERBER ET AL.

Examiner

John P. Lacyk

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3735

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (6,338,345) in view of Goupil (6,652,883).

Johnson et al discloses a device used to deliver a bulking prosthesis to the body.

Johnson et al teaches using an endoscope having a opening (58) or cavity for receiving tissue from the target site, the tissue is drawn into the opening by a vacuum and a needle is used to make a hole or puncture in the tissue and a "pushing agent" to push the prosthesis from the distal end of the tube through the hole. With respect to the bulking prosthesis Johnson et al teaches (column 16, lines 1-21) that it is well known to use a hydrophilic/hydrogel material as the bulking prosthesis. Also Johnson et al teaches (column 6, line 34-column 7, line 18) that the bulking prosthesis can take on a wide variety of shapes and sizes and that optimal dimensions are patient specific and can be determined through routine experimentation of one skilled in the art.

Johnson et al discloses a device for treating gastroesophageal reflux disease (GERD) and discloses the claimed device and method except for specifically teaching using the bulking prosthesis for treating urinary incontinence. Goupil et al teaches that it is well known to use a bulking material to treat a variety of problems including GERD and urinary incontinence. Therefore a modification of Johnson et al such that the

bulking prosthesis is used to treat urinary incontinence would have been obvious in view of Goupil et al which shows that it is well known to treat both with a bulking prosthesis.

3. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al and Goupil in view of Durgin (6,591,838).

Johnson et al discloses the claimed device except for the device includes a radiopaque material. Durgin discloses a bulking prosthesis and teaches that it is well known to use radiopaque materials such that the prosthesis is capable of being detected in the body. Therefore a modification of Johnson et al such that the prosthesis include a radiopaque material would have been obvious in view of the teachings of Durgin since this would allow the prosthesis to be viewed while inside the body to allow for proper placement and/or make sure the prosthesis does not move from its position.

4. Applicant's arguments filed 05/17/07 have been fully considered but they are not persuasive. Applicant argues that Johnson et al does not teach the device being sized for use in the urethral wall, this will be address below with respect to the rejection based upon Johnson et al and Goupil. Applicant argues, with respect to claim 10, that Johnson et al does not teach the shape being a partial cylinder having an inner radius sized to conform to the urethra, as pointed out in the rejection Johnson et al teaches that a wide variety of shapes and sizes that are determined by routine experimentation. Since it is known to use a variety of shapes this is considered to include a partial

cylinder depending on the particular shape that is best for the intended use of the device and in view of Goupil would have been obvious to one skilled in the art.

Applicant argues that there is no rational reason to modify Johnson et al to use the device in the urethral wall. As discussed above, Johnson et al discloses a bulking device that is used to treat GERD. Goupil discloses that it is well known to use a bulking material to treat both GERD and urinary incontinence. Therefore one skilled in the art would clearly be motivated to modify the device of Johnson et al such that it could be used to also treat urinary incontinence in view of the teachings of Goupil that show it is known to use a bulking material to treat both and Johnson et al teaches a device for implanting a bulking material into the body and there would have been a reasonable expectation of success.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

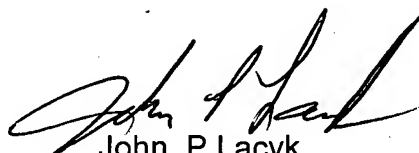
Art Unit: 3735

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



John P Lacyk  
Primary Examiner  
Art Unit 3735

J.P. Lacyk